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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MARCIANO PLATA, et al.,

Plaintiffs,

v.

ARNOLD SCHWARZENEGGER, et al.,

Defendants.

Case No. C01-1351 TEH

REPLY DECLARATION OF TERRY HILL, M.D. IN SUPPORT OF RECEIVER'S SUPPLEMENTAL APPLICATION NO. 2 FOR ORDER WAIVING STATE CONTRACTING STATUTES, REGULATIONS AND PROCEDURES, APPROVING RECEIVER'S SUBSTITUTE PROCEDURE FOR BIDDING AND AWARD OF CONTRACTS

I, Terry Hill, declare as follows:

1. I am currently the Chief Medical Officer for the California Prison Health Care Receivership and submit this reply declaration in support of the Receiver's Supplemental Application No. 2 for a Waiver of State Contracting Procedures ("Waiver Application"). The facts set forth herein are based on my own personal knowledge and, if called as a witness, I could competently testify thereto.
2. I have reviewed the opposition to the Receiver's application filed by plaintiffs' counsel and have the following observations and responses.
3. Plaintiffs have objected to the Waiver Application because, they contend, "two years is not required" to address asthma-related issues in the prisons; the Receiver has failed to explain the need for outside expertise; "other, shorter term actions… would reduce the risk to inmate patients;" remedial actions exist "which would far more directly address the problems identified;" and "adequate asthma treatment model(s)" exist and can be applied throughout CDCR. *See generally* Plaintiffs' Response To Receiver's Supplemental Application, etc. ("Pl. Resp.").
4. Plaintiffs also contend that an appropriate response to the problems posed should place "significant focus on lapses by primary care providers (PCPs) and RNs." Pl. Resp. at p. 3:3-4. Accordingly, they propose:

> (1) Identification… of the clinicians and nurses who failed to follow published guidelines and standards of care in the cases of preventable asthma deaths, and imposition of appropriate corrective or adverse action on those individuals;
>
> (2) Providing clinicians and nurses with adequate asthma evaluation and treatment guidelines and standards of care, and education regarding such matters…. These updated guidelines should be published and provided to all CDCR clinicians and nurses, policy or other changes should be made so that there is a clear expectation that clinicians and nurse will consider and follow the guidelines and standards as appropriate when evaluating and treating asthma patients;
>
> (3) Provide inmate-patients who have asthma with educational materials regarding their disease….
>
> (5) [*sic*, #4 missing in the original] Review of asthma-related deaths should continue, and review of asthma related emergency department and hospital admissions should be instituted, so as to identify additional clinician failures and

other factors contributing to morbidity and mortality. Pl. Resp. at p. 3-4.

5. I will address each of plaintiffs' comments.

6. In contending that "two years" is not required to complete the Asthma Initiative, plaintiffs simply misunderstand the Receiver's Request for Proposal ("RFP") and the Initiative itself. First, and foremost, the primary work to be accomplished is to be completed within about 12 months. On November 19, 2007, the Receiver posted "Questions and Answers" pertaining to the RFP for the Asthma Initiative. *See* http://www.cprinc.org/docs/projects/CPR_RFP_AsthmaInitiativeQaA111907.pdf. The Receiver explained in response to a number of questions that the Initiative was on fast track that should be largely completed within a year. The Receiver suggested to proposed bidders that they should begin with the prisons that have implemented the Maxor pharmacy information system, GuardianRx. By June 2008, six prisons are scheduled to be using GuardianRx. But the Receiver has emphasized that:

> *[T]he Asthma Initiative will move at a faster pace than GuardianRx implementation. Furthermore, the Asthma Initiative need not necessarily progress incrementally, one or two facilities at a time.*
>
> In addition to implementing the asthma package where GuardianRx is in place, the contractor should be able to engage facilities with some asthma interventions prior to GuardianRx implementation and then assist these facilities through the GuardianRx transition. Development and testing of this second package will also be essential to successful movement from intensive engagement strategies, including use of contractor experts on site, to less-intensive, rapid dissemination strategies that do not require on-site visits. . . . *[T]he limited heterogeneity and autonomy of the prisons should allow faster implementation of practice improvement than could be achieved among separate organizations.* Furthermore, as the project progresses, all the regional medical directors and directors of nurses and all the physician and nurse consultants who report to them will become familiar with the Asthma Initiative interventions and will act as change agents on their behalf.
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> ***
>
> As mentioned above, *the contractor should anticipate developing less-intensive, rapid-spread dissemination strategies to engage a larger volume of facilities in the final phase of the project. This final phase should be at least on the way to completion at the 12-month point.*

"Questions and Answers," pp. 2, 6.

7. Most health care organizations with multiple delivery sites select a handful of sites to

engage in a "collaborative" project of this type for about a year. Upon completion of the collaborative, the organization then moves into a dissemination phase to reach the remainder of its sites. While clinical guidelines attempt to be universally applicable, implementation is always local, so organizations generally want to test interventions in their typical settings before making major commitments of resources. This has been, of course, the Receiver's approach all along: pilot first before wider implementation.

8. The timeframe proposed by the Receiver, *i.e.*, roughly one year for completion of most of the clinical interventions, is standard in the health care industry for initiatives of this type. The Health Resources and Services Administration ("HRSA"), an agency of the U.S. Department of Health and Human Services, sponsors the HRSA Health Disparities Collaboratives that focus on conditions disproportionately affecting people who are uninsured, isolated or medically vulnerable. The collaboratives enroll community health centers and teach the Chronic Care Model. As described on the federal website (www.healthdisparities.net), the collaboratives require both hard work and sufficient time:

> Collectively these systems facilitate communication, coaching and infrastructure support so that learning can be shared and improvements accelerated.... Organizations will typically spend about 12 – 13 months learning and applying the models to improve their healthcare delivery systems by adapting the general principles to their unique environments and communities.... As the Health Centers embed their work into their organizational frameworks and continue improvements, they are supported by continued coaching and feedback. Collaborative participants will tell you that change is difficult and that hard work is required.

9. The HRSA Disparities Collaboratives illustrate the usual time required for practice change and the effort required to bring about such change. Indeed, all of the vendors responding to the RFP have recognized that the Receiver's timeline is quite demanding.

10. Although the Receiver is insisting that the bulk of the clinical interventions be done in one year, the vendor selected must remain available for further quality data analysis

for up to two years. Therefore, the contract term is for two years.

11. Pertinent to the plaintiffs' objection regarding the need for outside expertise, HRSA offers outside support to the clinics participating in its collaboratives precisely because change is difficult, and "guideline implementation lags in many practices across the country." The Court should note that clinics participating the HRSA collaboratives include some of the best in the nation; clinics must complete a rigorous application process before they are allowed to participate. The CDCR's clinics, by contrast, do not share the same internal stability and expertise. Moreover, HRSA itself sought outside expertise from the Institute for Healthcare Improvement in designing its collabortives interventions. The need for outside expertise in projects like the Asthma Initiative is also illustrated by Kaiser Permanente, which has one of the finest internal education departments in the world. Kaiser routinely turns to outside consultants for help with system redesign. For the Kaiser primary care model innovation project, launched in September 2005, Kaiser also engaged the Institute for Healthcare Improvement as consultants to help lead lengthy collaboratives (see http://xnet.kp.org/permanentejournal/winter07/people.html). If Kaiser Permanente and the best clinics in the country require time and outside expertise in order to change practice and improve care outcomes, it would be unfair to insist that an organization as dysfunctional as CDCR must use only internal resources.

12. Plaintiffs' objection that the Receiver is not using shorter-term, remedial actions to address asthma-related deaths is based upon, or seeks to create, the erroneous impression that the Receiver is failing to take such actions. In fact, the Receiver's reports and the Plan of Action itself detail many interventions which are ongoing and pertinent to asthma care. To mention but a few:

- The death review analysis itself and asthma care performance in particular have been discussed at length at statewide and regional meetings of both the institutional directors of nursing and the chief medical officers.

- As noted in the death review analysis: "As of July 2007, 62 CDCR practitioners (56 MDs and DOs and 6 Nurse Practitioners) have had adverse action taken by the PPEC. Of these, 41 were initiated by the death reviews." This activity continues apace.
- There have been intense efforts to get qualified physicians and nurses at both line-staff and supervisory levels who will focus attention on "red flag" symptoms.
- The statewide clinical leadership has already initiated improvements in emergency response, and those efforts will multiply in the new emergency response initiative.
- The Pharmacy and Therapeutics Committee not only wrote a new asthma medication guideline, the guideline was discussed with clinical leadership from each institution and distributed throughout the medical staff.
- The statewide leadership distributed a teaching toolkit on asthma developed for CDCR by UC San Diego.

13. Plaintiffs also believe that adequate asthma treatment models and chronic care programs currently exist within CDCR and that the Receiver should simply require compliance with them. Unfortunately, no prison in California is even attempting to meet the standards of the National Asthma Education and Prevention Program ("NAEPP") Expert Panel Report (Update 2007). None is using the panel's classification system, and none is using individualized written asthma action plans, which have proven critical to improving outcomes. More broadly, plaintiffs are clearly unfamiliar with the chronic care *model* described in the Asthma Initiative RFP as distinct from a "chronic care program" that simply tries to ensure that patients with chronic illness return regularly to see a provider who tries to follow a simple guideline.

14. It is undoubtedly true that some CDCR prisons provide better asthma care than others. Unfortunately, there are no data specific to asthma available, other than mortality

(which is statistically limited by the low-number problem), to suggest which prisons perform actually perform better. Our knowledge of variations in performance is principally via managerial impressions. Furthermore, local performance tends to be leadership-dependent. Even competent line-level clinicians cannot overcome profound system problems, so if good nursing and physician managers leave—or even divert their attention—then asthma care will break down in the absence of quality monitoring.

15. The Chronic Care Model is a dramatic departure from the physician-centric, episodic model that relies primarily upon the interaction between physician and patient. The Chronic Care Model involves the patient and multiple staff members learning new roles and using data in new ways, supported by information technology and quality measures. Its success in diverse settings has led multiple systems to initiate practice change initiatives to make the Chronic Care Model a reality, as illustrated above by the efforts of HRSA and Kaiser.

16. Just as plaintiffs misunderstand the Asthma Initiative itself, the solutions they propose fall far short of those sought in the Asthma Initiative; indeed, they fall short of the interventions already initiated.

17. Plaintiffs propose taking corrective or adverse action against the individual nurses and physicians who were involved in the six preventable asthma deaths reported in the review of preventable deaths. Pl. Resp. at p. 3:11-14. In fact, the appropriate nursing and physician committees have already reviewed the care in these six cases and have taken appropriate actions. While appropriate adverse action against some of these clinicians is and was necessary, that alone will not result in significant improvement in asthma care system-wide.

18. Plaintiffs next propose providing clinicians with guidelines and education and clear expectations. Pl. Resp. at 3:15-26. Within the limits of the educational and managerial infrastructure currently in place, this has also already occurred.

19. Plaintiffs propose providing asthma patients with educational materials. As noted in paragraph 13, above, such an approach falls far short of developing individualized written asthma action plans, as required by the NAEPP Expert Panel Report . Moreover, the Receiver is already developing education programs for the inmate-patients. In the Plan of Action, the Receiver has committed to producing "cultural and linguistically appropriate patient education resources." Specifically in relation to asthma, the Receiver's Plan of Action commits to "Develop and pilot appropriate inmate peer education programs, *e.g.*, for diabetes and asthma."

20. Plaintiffs propose that review of asthma deaths continue—these reviews are continuing and will continue —and that reviews of asthma-related emergency visits and hospitalizations commence—they will.

21. If the plaintiffs' primary concern is whether the Receiver has moved as fast as possible with remedial actions directed at asthma in the prison population, I can assure the Court that he has. The interventions mentioned above are only the most specific to asthma among all the interventions that have been launched to build a functional medical care delivery system.

22. The underlying assumption of the plaintiffs' various objections appears to be that all that is necessary is that the Receiver should be able to promulgate an asthma guideline, insist that staff follow it, and asthma care will then be satisfactory. This logic is quite appealing, though flawed. In the early 1990s, many health care professionals agreed with that logic, and the U.S. Congress funded a federal agency to create and distribute clinical guidelines. In its 2001 volume, *Crossing the Quality Chasm*, the Institute of Medicine ("IOM") noted that "Guidelines have proliferated at a rapid pace during the last decade." Unfortunately, they concluded, "Developing and disseminating practice guidelines alone has minimal effect on clinical practice." Fortunately, we now know a great deal about the causes for that failure. As noted by the IOM:

> Ensuring that new knowledge is incorporated into practice… requires a thorough understanding of how change is managed most effectively in health care, including the barriers to and facilitators of change. Knowledge about why guidelines are or are not used is accumulating, and experts now better understand the circumstances in which such strategies as education, administrative changes, incentives, penalties, feedback, and social marketing are likely to be effective and why the translation of research findings to date has been characterized as "slow and haphazard."

23. By taking the foregoing factors into account, we are now making significant progress in the quality of care and care outcomes. The AHRQ study called *Closing the Quality Gap*,[1] cited in the Receiver's waiver request, "found that the greater the number of QI [Quality Improvement] strategies, the more likely a study was to report improvements in clinical outcomes. In particular, we found that patient and provider education interventions that also included an element of organizational change (for example, by adding pharmacists to the clinical team or by instituting an information system that facilitates reporting of clinical information between patients and providers) were often associated with improvements in outcomes for patients."

24. We now know how to improve asthma care, and the Asthma Initiative will incorporate all the elements required for success.

25. Finally, and of particular importance to the prison medical care system, the Asthma Initiative is not the only quality improvement initiative the Receiver will undertake; it is merely the first. But as the first it occupies an important place in the Receiver's approach to quality improvement. The Asthma Initiative will introduce all of the elements required to repair this broken system generally. The processes, education, training and approaches implemented through the initiative will lay down the railway tracks not just for the Asthma Initiative "train," but for the other quality initiative trains the Receiver intends to introduce as he undertakes to improve clinical conditions and processes throughout the prison system.

I declare under penalty of perjury under the laws of the State of California that the

[1] Bravata DM, et al. Asthma Care. Vol 5 of: Shojania KG, et al., editors. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Technical Review 9 AHRQ. January 2007.

foregoing is true and correct.

Dated: December 21, 2007

/s/
Terry Hill, M.D.

I hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/s/) within this efiled document.

/s/
Martin H. Dodd
Attorneys for Receiver Robert Sillen